

**Spikman JM, Boelen DH, et al. Effects of a multifaceted treatment program for executive dysfunction after acquired brain injury on indications of executive functioning in daily life. JINS 2010;16:118-129.**

Design: Randomized clinical trial

Population/sample size/setting:

- 75 patients (50 men, 25 women, mean age 42) treated for executive dysfunction following nonprogressive acquired brain injury (ABI) at a university neurology department in the Netherlands
- Eligible patients were between 17 and 75, were at least 3 months after onset, were living at home, and were referred for executive problems reported by themselves or by their proxies
  - o Executive dysfunction was measured by means of a questionnaire and a standardized test in the “low average” range, or with a score at least 15 points (1 standard deviation) lower than their IQ
- Exclusion criteria were severe comorbidity (aphasia, amnesic syndrome, neglect), severe psychiatric problems, neurodegenerative disease, and substance abuse

Main outcome measures:

- Of the 75 patients enrolled at baseline, 33 had TBI, 32 had stroke, and 10 had other diagnoses
- Randomized to either an experimental intervention (n=38) or to a control intervention (n=37)
- Experimental and control interventions were administered in the form of 20-24 one hour treatment sessions, attended twice per week for 3 months, supervised by a rehabilitation neuropsychologist
- Experimental intervention was based on a conceptual framework of 8 aspects of executive function: self-awareness, goal-setting, planning, self-initiation, self-monitoring, self-inhibition, flexibility, and strategic behavior
  - o Sessions were organized in three stages, each lasting several sessions; the three stages were information/awareness, goal setting/planning, and initiation/execution/regulation
  - o Focus of training was to set goals and to break them down into sub-goals, placing these in correct order, dealing with sudden situational changes that arise under different conditions
- Control intervention was a computerized cognitive training package of repetitive exercises, aimed at improving reaction speed, attention, memory, and planning
  - o Most tasks did not require supervision, but a therapist was available to provide support when needed; participants had some ability to select the exercises which would facilitate their treatment goals
- Primary outcome was the Role Resumption List (RRL), a manual published in Dutch by the sponsoring university

- RRL is based on structured interviews with the patient and assesses changes in amount and quality of activities in 4 domains: vocational function, social interaction, leisure activity, and mobility
  - RRL was administered by blinded observers at baseline, at the end of the 3 months of treatment, and at 6 months post-treatment
- Several adjunctive test measures were administered at intervals, but one, the Executive Secretarial Test (EST), was considered especially important, and was administered only once, at the 6 month follow-up
  - EST is a 3 hour test involving organization of multiple tasks with interruptions, deadlines, and delayed intentions
  - EST was given only once because repeated administration would entail an admixture of treatment effects and test repetition effects
  - EST has three subscales, one for initiative (actions initiated without prompting), prospective (actions carried out at a later stage), and executive (actions carried out at all)
- At the 3 month evaluation, the experimental group had greater improvement on the RRL than the control group, and this advantage was seen again at the 6 month evaluation
- On the EST, the treatment group had higher scores than the control group on the prospective and executive subscales; the scores on the initiative subscale did not differ between treatment groups
  - The EST was also given to 57 volunteer healthy control subjects; the control group scored lower than the healthy volunteers on all three subscales of the test, but the experimental group scored about equal to the healthy controls on the initiative and prospective subscales
- Most of the adjunctive test batteries did not differ between groups; these included some conventional neuropsychological tests like the Stroop, the Trail Making Test, and memory tests

#### Authors' conclusions:

- A multifaceted treatment for executive dysfunction after acquired brain injury led to significant improvements in several indications of daily life executive function, lasting at least 6 months post-treatment, compared to a control intervention focusing on cognitive improvement
- Other conventional neuropsychological tests of well-being, cognition, and executive function improved over time, but no difference was found between the experimental and control interventions
- Several aspects of the experimental intervention may account for its benefits, including attention to transferring skills to daily life, increasing self-awareness, and addressing problems with self-initiative
- The lack of effects on conventional neuropsychological testing shows the difficulty of assessing daily life function with these tests
- Multifaceted treatment can produce significant benefits if it is aimed at improving activity and social participation and is tailored to the individual patient

Comments:

- Although the between-group comparison seems to have controlled potential sources of bias adequately (randomization and blinding), the importance of the actual effect size is not easily estimated
  - o The instrument (the RRL) used to measure the outcome is not available in English, and the RRL, unlike the EST, was not administered to the healthy controls
  - o There may be a set of norms for the RRL, but they are not reported
- Because the etiologies were mixed between TBI, stroke, and “other,” there is no estimate of baseline severity (i.e., the GCS is not part of the baseline assessment of stroke severity, and the severity of the TBI subgroup is not reported)
- Even though the experimental group in Table 1 appears to have more TBI patients than the control group, the difference is not statistically significant
- The internal validity of the study is satisfactory, but the external validity is uncertain in the absence of more information of injury severity
  - o The patients were required to be living at home, indicating that they were likely to be mildly impaired at the time of enrollment, and that their activities of daily living and other basic cognitive functions were satisfactory
- It is not explicitly stated, but it appears that both groups had individual treatment sessions (not in groups)

Assessment: adequate for evidence that a multifaceted intervention aimed at several aspects of executive function can lead to lasting improvement in these functions